K024326
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Spinal Concepts, Inc.
Ant-Cer Dynamic Anterior Cervical Plate System

510(k) Summary of Safety and Effectiveness

JAN 2 3 2003

SUBMITTED BY	Spinal Concepts, Inc. 5301 Riata Park Court, Bldg. F Austin, TX 78727
ESTABLISHMENT REGISTRATION NUMBER	1649384
CONTACT PERSON	Primary Lisa Peterson Regulatory Affairs Specialist Phone: 512-918-2700 Fax: 512-249-6734 Alternate David Hooper, Ph.D. Director, Clinical and Regulatory Affairs Phone: 512-918-2700 Fax: 512-249-6734
DATE PREPARED	December 20, 2002
CLASSIFICATION NAME	KWQ: Spinal Intervertebral Body Fixation Orthosis. Class II.
COMMON NAME	Spinal Fixation System
PROPRIETARY NAME	Ant-Cer Dynamic Anterior Cervical Plate System
PREDICATE DEVICE	Spinal Concepts SC-AcuFix Anterior Cervical Plate System, (K990005 and K013979). This is a design modification per established design control procedures.

DEVICE DESCRIPTION
The Ant-Cer Dynamic Anterior Cervical Plate System consists of various sizes of bone plates, screws and surgical instruments. The screws are used to secure the plates to the vertebral bodies of the cervical spine through an anterior approach. The plates have an integrated locking mechanism that captures the screw upon full insertion, preventing screw-backout. The Ant-Cer system is a dynamic plate system that provides for uni-directional axial movement to ensure postoperative load sharing between the plate and graft. Plates and screws are manufactured from titanium alloy (ASTM F-136) and may be supplied sterile or non-sterile.

INDICATIONS
The Ant-Cer Dynamic Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumor, spondylolisthesis, spinal stenosis, deformity (i.e., scoliosis, kyphosis, lordosis), pseudarthrosis, and failed previous fusions.

MECHANICAL TEST DATA
Mechanical testing data, including data collected in accordance with ASTM 1717, was collected to verify that the design changes met established design requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2003

Spinal Concepts, Inc.
Ms. Lisa Peterson
Regulatory Affairs Specialist
12012 Technology Boulevard, Suite 100
Austin, Texas 78727

Re: K024326
Trade Name: Ant-Cer Dynamic Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3050
Regulation Name: Appliance, fixation, spinal intervertebral body
Regulatory Class: II
Product Code: KWQ
Dated: December 20, 2002
Received: December 26, 2002

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name:
Spinal Concepts, Inc. **Ant-Cer Anterior Cervical Plate System**

Indications for Use:

The Ant-Cer Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumor, spondylolisthesis, spinal stenosis, deformity (i.e., scoliosis, kyphosis, lordosis), pseudarthrosis, and failed previous fusions.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024326

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number _____